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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	William M. Kleinfelter	
Serial No.	:	09/348,774	Examiner: Robert W. Morgan
Filed	:	July 7, 1999	Group Art Unit: 2166
Title	:	PRESCRIPTION DATA PROCESSING SYSTEM FOR DETERMINING NEW THERAPY STARTS	

Commissioner for Patents
Washington, D.C. 20231

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REMARKS IN RESPONSE TO OFFICE ACTION

Sir:

These remarks are submitted to address the issues raised in the Final Office Action dated February 14, 2002 and also discussed in a telephonic interview with the Examiner on August 27, 2002 (hereinafter, the "Interview").

Claims 1-49 are pending in the application.

In section 3 of the Final Office Action, the Examiner rejects claims 1-49 under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,950,630 to Portwood et al. (hereinafter, "Portwood"). This rejection is respectfully traversed.

Although Portwood and the method described in the present application both relate to operations performed on drug prescription data for patients, Portwood and the present method perform very different operations on such data to achieve very different purposes. Portwood describes a system which compares data describing drug dosages prescribed for a patient with data from

pharmaceutical companies describing recommended dosage ranges for various drugs to determine whether the drug dosages prescribed for the patient comply with the recommended dosage ranges for the prescribed drugs. Thus, the Portwood system ensures the integrity of a drug prescription created by a physician for a patient by verifying that the prescription meets recommended standards for the prescribed drug. (Col. 1, lines 6-12).

On the other hand, the present method compares data describing a first drug prescribed for a patient with data describing drugs previously prescribed for the same patient to determine whether the first drug is a new therapy start or a therapy switch for that patient. Thus, the present method is useful to pharmaceutical companies in determining when their marketing efforts have been successful in (a) persuading a health care specialist to prescribe a new drug therapy to a patient for a new illness, or (b) persuading a health care specialist to prescribe a therapy switch, e.g., a new drug for an existing illness for which the patent had been taking a different drug.

Portwood describes a system including a central server computer, a prescriber computer, a patient message unit, a prescription delivery system, and a payment system. (Col. 4, line 55 to Col. 6, line 12 and Fig. 1). The central server computer stores pharmaceutical data for various drugs which includes, for each drug, information such as the drug's Generic Product Identifier (GPI) or National Drug Code (NDC) and recommended dosage and duration ranges for the drug as provided by pharmaceutical companies to the U.S. FDA (Col. 7, lines 52-67).

In Portwood, a prescriber enters, at the prescriber computer, patient data and prescription data for drugs being prescribed for the patient. (Col. 6, lines 50-54 and Col. 8, lines 5-11). Patient data includes information such as the patient's name, social security number, and medical

history such as prior adverse reactions to specific drugs. (Col. 8, lines 38-48). Prescription data includes such information as the patient's identification (e.g., social security number), the prescription GPI or NDC, and a prescribed dosage schedule. The prescription data includes similar information for other drugs the patient is currently taking. (Col. 8, lines 18-26). The prescriber computer then retrieves, from the central server computer, pharmaceutical data relating to each prescribed drug as well as each other drug the patient is currently taking. (Col. 9, lines 33-43 and Col. 10, lines 5-11). Using the pharmaceutical data, the prescriber computer checks each prescription to determine whether it is within the recommended dosage and duration ranges. (Col. 10, lines 12-17 and Col. 14, lines 52-60). The prescriber computer also uses the pharmaceutical data to determine whether any prescribed drug will cause an unacceptable reaction with any other prescribed drug. (Col. 15, lines 6-60). In addition, the prescriber computer searches the patient data to determine whether the patient has ever reported any adverse reaction to any drug being prescribed. (Col. 15, lines 61-67). Thus, the Portwood system uses pharmaceutical data to ensure the integrity of drug prescriptions created by a physician for a patient by verifying that the prescriptions meet recommended drug dosage and duration ranges, that the prescriptions do not cause any unacceptable interactions with each other, and that the patient has not previously reported an adverse reaction to any of the prescriptions.

The present method does not check prescriptions against pharmaceutical data to verify their integrity, but rather, compares prescriptions against previous prescriptions for the same patient to determine whether a new therapy start has begun. Specifically, independent claims 1, 10, and 19 recite comparing a patient identifier from a first prescription record with the patient identifiers of pre-stored records containing information on drugs previously prescribed for patients to find a pre-stored record

having a patient identifier that matches the patient identifier of the first record, and then comparing a first name of a first prescription drug of the first record with a second name of a second prescription drug from the matching pre-stored record, and then identifying the first prescription drug as a new therapy start if the first name is not substantially identical to the second name. Also, independent claims 20, 29, and 39 recite comparing the patient identifier of a first prescription data record to the patient identifiers of each of a plurality of pre-stored records, each of which comprises a patient identifier identifying a patient and a drug identifier identifying a drug prescribed to the patient, to find a pre-stored record having a patient identifier matching the patient identifier of the first record, and then determining whether the drug identifier of the matching pre-stored record is related to the drug identifier of the first record, and then identifying the drug prescribed as a new therapy start if the drug identifier of the first record is not related to the drug identifier of the matching pre-stored record.

Thus, a computer system operating according to the method of the present invention can be used to determine when a drug has been newly prescribed for a patient. Such information is useful where, for example, a pharmaceutical company measures the effectiveness of its sales efforts based on how often medical professionals prescribe the company's drugs as new therapies. The Portwood system simply does not provide information on new therapy starts, because it is designed for an entirely different purpose, to ensure the integrity of prescriptions, e.g., drug dosage and duration ranges, based on recommended dosage and duration ranges from pharmaceutical data.

In light of the above, and as discussed in detail below, Applicant respectfully submits that the Examiner's citations to Portwood in section 3 of the Final Office Action, and as indicated in the Interview, do not meet the limitations of the claimed invention.

As discussed above, independent claims 1, 10, and 19 recite comparing a patient identifier from a first prescription record with the patient identifiers of pre-stored records containing information on drugs previously prescribed for patients to find a pre-stored record having a patient identifier that matches the patient identifier of the first record, and then comparing a first name of a first prescription drug of the first record with a second name of a second prescription drug from the matching pre-stored record. Also, independent claims 20, 29, and 39 recite comparing the patient identifier of a first prescription data record to the patient identifiers of each of a plurality of pre-stored records, each of which comprises a patient identifier identifying a patient and a drug identifier identifying a drug prescribed to the patient, to find a pre-stored record having a patient identifier matching the patient identifier of the first record, and then determining whether the drug identifier of the matching pre-stored record is related to the drug identifier of the first record. In section 3 of the Final Office Action and as discussed in the Interview, the Examiner asserts that four passages from Portwood meet the second comparing limitation from claims 1, 10, and 19 as well as the determining limitation from claims 20, 29, and 39. Each passage will be discussed below in turn.

The first passage from Portwood that the Examiner cites as meeting the second comparing limitation from claims 1, 10, and 19 as well as the determining limitation from claims 20, 29, and 39, reads as follows:

> ...If server system A is provided with a data base containing the payor identification and drug cost charged by the prescription delivery service D, then server system A can directly generate and transmit the billing statement to the payment system E.
>
> Alternatively, the prescription delivery system D and the payor system E could be directly linked by computers to transmit the billing statement and to make payments directly to the prescription delivery system D. ...

(Col. 6, lines 5-10).

In this first passage cited above, Portwood describes alternative embodiments in which the central server computer, the prescription delivery service, and the payment system can generate and transmit billing statements. There is no description or inference in this first passage of comparing a first name of a first drug of a first record with a second name of a second drug from a matching pre-stored record as recited in claims 1, 10, and 19. In addition, there is no description or inference in this passage of determining whether the drug identifier of a matching pre-stored record is related to the drug identifier of a first record as recited in claims 20, 29, and 39. Consequently, Applicant respectfully submits that the above passage does not meet these limitations recited in claims 1, 10, 19, 20, 29, and 39.

The second passage from Portwood that the Examiner cites as meeting the second comparing limitation from claims 1, 10, and 19 as well as the determining limitation from claims 20, 29, and 39, reads as follows:

> 3. Prescription information for the patient is entered into the system by the prescriber. This information includes, but is not limited to, drug name, units and strength, prescription signature, refills, dosing mode, and a date and time that the first dose is to be administered. ...

(Col. 6, lines 50-54).

In this second passage cited above, Portwood describes the type of prescription information provided by a prescriber for a patient. There is no description or inference in this second passage of comparing a first name of a first drug of a first record with a second name of a second drug from a matching pre-stored record as recited in claims 1, 10, and 19. In addition, there is no description or inference in this second passage of determining whether the drug identifier of a matching

pre-stored record is related to the drug identifier of a first record as recited in claims 20, 29, and 39. Consequently, Applicant respectfully submits that the second passage above does not meet these limitations recited in claims 1, 10, 19, 20, 29, and 39.

The third passage from Portwood that the Examiner cites as meeting the second comparing limitation from claims 1, 10, and 19 as well as the determining limitation from claims 20, 29, and 39, reads as follows:

> ... FIGS. 3A and 3B are preferred software subroutines used in the prescriber computer system B to check whether the prescribed drug is within the recommended dosage range and whether the prescribed drug creates any objectionable interaction with other drugs which the patient is taking, respectively. FIG. 3A-1 is a more preferred software subroutine within the dosage range check routine to determine if the prescribed drug regimen is within the recommended daily dosage range and within the recommended unit dosage. FIG. 3A-2 is a more preferred software subroutine to determine if in the standard medication mode, the total dosage is within the recommended duration range.

(Col. 7, lines 40-51)

In the third passage cited above and in the figures referred to in the passage, Portwood describes a procedure for comparing drug therapy dosages and durations prescribed for a patient against recommended dosages and durations for the prescribed drugs, as described by the pharmaceutical data, to determine whether the prescribed dosages and durations fall within the recommended dosages and durations. There is no description in this third passage or the figures referred to therein of comparing a first name of a first drug of a first record with a second name of a second drug from a matching pre-stored record as recited in claims 1, 10, and 19. In addition, there is no description in this third passage or the figures referred to therein of determining whether the drug identifier of a matching pre-stored record is related to the drug identifier of a first record as recited in

claims 20, 29, and 39. Consequently, Applicant respectfully submits that the third passage above and the figures referred to therein do not meet these limitations recited in claims 1, 10, 19, 20, 29, and 39.

As described previously, in order to perform the comparison procedure described in the third passage above, the prescriber computer retrieves, from the central server computer, pharmaceutical data relating to each prescribed drug. Although this retrieval may involve comparisons of drug identifiers of prescribed drugs with drug identifiers in records at the central server in order to find those records at the central server containing pharmaceutical information related to the prescribed drugs, such comparisons do not meet the second comparing limitation from claims 1, 10, and 19 or the determining limitation from claims 20, 29, and 39.

As described previously, the second comparing limitation from claims 1, 10, and 19 compares a first name of a first prescription drug of a first record with a second name of a second prescription drug from a ***matching*** pre-stored record, where the pre-stored record has been previously found to be matching if it contains a patient identifier that matches the patient identifier of the first record. Similarly, the determining limitation from claims 20, 29, and 39 determines whether the drug identifier of a first record is related to the drug identifier of a ***matching*** pre-stored record, where the pre-stored record has been previously found to be matching if it contains a patient identifier that matches the patient identifier of the first record. Thus, the second comparing limitation from claims 1, 10, and 19 and the determining limitation from claims 20, 29, and 39 involve comparisons of new prescription data for a patient with previously stored prescription data for the same patient.

With Portwood, however, any comparisons that may be performed in connection with the retrieval described above involve comparisons of new prescription data for a patient with

previously stored generic pharmaceutical data that is not specific to any particular patient. Consequently, Applicant respectfully submits that the retrieval operation of Portwood described above does not meet the second comparing limitation from claims 1, 10, and 19 or the determining limitation from claims 20, 29, and 39.

The fourth passage from Portwood that the Examiner cites as meeting the second comparing limitation from claims 1, 10, and 19 as well as the determining limitation from claims 20, 29, and 39, reads as follows:

> Prescriber CPU 7 is programmed to then search the pharmaceutical data to determine in step 631D if there is a recommended maximum prescribing duration. If none is found, the prescriber CPU 7 is programmed to generate and transmit to monitor 10 in step 631E a message, and then proceed to step 631F. The message would indicate that there is not a recommended maximum prescribing duration (See Message Number 16).
>
> If a recommended minimum prescribing duration was found in step 631F, then prescriber CPU 7 is programmed to determine in step 631F if the calculated prescribing duration is less than the recommended minimum. ...

(Col. 14, lines 52-60).

In the fourth passage cited above, Portwood provides a more detailed description of the procedure for comparing prescribed drug therapy durations against recommended durations from pharmaceutical data that was introduced in the third passage previously cited. As with the third passage, this fourth passage contains no description of comparing a first name of a first drug of a first record with a second name of a second drug from a matching pre-stored record as recited in claims 1, 10, and 19. In addition, there is no description in this fourth passage of determining whether the drug identifier of a matching pre-stored record is related to the drug identifier of a first record as recited in

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In Re Application of: William M. Kleinfelter
Serial No.: 09/348,774
Filed: July 7, 1999 Group Art Unit: 2166
Title: PRESCRIPTION DATA PROCESSING SYSTEM FOR DETERMINING NEW THERARPY STARTS

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Sincerely Yours,

Frederick Yu
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Application No.: 09/348,774
Examiner: Robert W. Morgan
Filed: July 7, 1999 Group Art Unit: 2166
Attorney Docket No.: 3207/22
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First Named Inventor	William M. Kleinfelter
Group Art Unit	2166
Examiner Name	Robert W. Morgan
Total Number of Pages in This Submission: 24	**Attorney Docket Number** 3207/22

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